

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR
SYSTEMS PRODUCTS LIABILITY
LITIGATION

Master File No. 2:12-MD-02327
MDL 2327

ETHICON WAVE 3 CASES LISTED IN
EXHIBIT A

JOSEPH R. GOODWIN U.S. DISTRICT
JUDGE

**MEMORANDUM IN SUPPORT OF DEFENDANTS' SUPPLEMENTAL MOTION TO
EXCLUDE AND NOTICE OF ADOPTION OF PRIOR DAUBERT MOTION AND
REPLY BRIEF OF MICHAEL THOMAS MARGOLIS, M.D. FOR WAVE 3**

Defendants Ethicon, Inc., Ethicon, LLC, and Johnson & Johnson (collectively, "Ethicon"), submit this supplemental memorandum in support of their motion to exclude certain opinions of Dr. Michael Thomas Margolis for Ethicon Wave 1 cases, Dkt. Nos. 2029 (motion), 2031 (memorandum in support) and supporting Reply brief, Dkt. 2212, which have been adopted with respect to the cases set forth in Exhibit A of Ethicon's notice of adoption, filed contemporaneously herewith.

INTRODUCTION

In its Wave 1 Motion to Exclude Dr. Margolis, Ethicon moved to exclude Dr. Margolis's opinions and testimony on the following bases, which are renewed for Wave 3: (1) Dr. Margolis should not be permitted to testify on Defendants' knowledge, state of mind, and alleged bad acts; (2) Dr. Margolis was not qualified to testify regarding product warnings; (3) Dr. Margolis's opinions on degradation and laser-cut versus mechanically-cut mesh lacked support in the medical literature; (4) Dr. Margolis simply regurgitated information contained in Ethicon's internal documents; (5) Dr. Margolis was not qualified to testify on product marketing; (6) Dr. Margolis's sweeping opinions on the TVT and TVT-O had no reliable basis; (7) Dr. Margolis

was not qualified to testify regarding biomaterial properties of mesh; (8) Dr. Margolis should not be permitted to testify using extreme exaggeration and hyperbole; and (9) Dr. Margolis should not be permitted to render undisclosed opinions. This Court held that (1) Dr. Margolis is not qualified to opine about what Ethicon's Instructions for Use (IFU) should include; (2) Dr. Margolis's testimony on complications resulting from laser-cut mesh as opposed to mechanically-cut mesh is admissible; (3) Dr. Margolis will not offer opinions regarding Ethicon's products allegedly causing cancer; (4) Dr. Margolis's testimony on safety and efficacy is reliable because he cites to medical literature in support of his opinion; (5) Dr. Margolis is qualified to opine on biomaterials properties of mesh; and (6) Dr. Margolis is not qualified to testify on medical device manufacturers' marketing practices; as well as entering its order on recurring issues excluding, among other things, any state-of-mind and legal-conclusion expert testimony, as well as any testimony that is solely a conduit for corporate information and documents. (Dkt. 2681).

In addition to the issues raised in Wave 1, this Court should preclude Dr. Margolis from offering opinions regarding the alleged differences between mechanically cut mesh and laser cut mesh as well as his other general opinions regarding alleged degradation of Ethicon's mesh products. In addition to the arguments set forth in Ethicon's briefings filed against Dr. Margolis for Ethicon Wave 1 cases, Ethicon submits that opinions related to degradation, including opinions related to the degradation of mechanically cut versus laser cut mesh, are unreliable.

LEGAL ARGUMENT

I. The Court should exclude Dr. Margolis's opinions on mechanically cut versus laser cut mesh.

Dr. Margolis criticizes Defendants' mechanically cut mesh (MCM) as inferior to laser-cut mesh (LCM), in that LCM allegedly experiences less particle loss than MCM. Ex. B, Rule 26

Expert Report of Dr. Michael Thomas Margolis on TVT at 16-18 (“TVT Rep.”); *see also* Ex. C, Rule 26 Expert Report of Dr. Michael Thomas Margolis on TVT-O at 16-18 (“TVT-O Rep.”). Defendants respectfully submit that such testimony be excluded. In his reports, Dr. Margolis opines that “the method by which mesh is cut significantly impacts how that mesh will perform during the implantation surgery and while implanted in a woman’s body.” TVT Rep. at 16; TVT-O Rep. at 16. Dr. Margolis’s general opinion is that mechanically cut mesh causes fraying and particle loss, and is more likely to rope, curl, and deform when stretched or placed under tension, TVT Rep. at 17; TVT-O Rep. at 17. Defendants moved to exclude this opinion in their original Motion, arguing that Dr. Margolis has admitted that he does not have scientific literature to support these theories. (Dkt. 2031, Mem. in Supp. of Mot. to Exclude Certain Opinions of Michael Thomas Margolis, M.D., at 8).

Although the Court has previously observed that Dr. Margolis “does support his opinions with citations to scientific studies and articles,” (Dkt. 2681, Memorandum Opinion and Order (*Daubert* Motion re. Michael Thomas Margolis, M.D.) (S.D. W. Va. Aug. 30, 2016), at 6-7), the only “literature” that Dr. Margolis cites in the sections of his reports about laser cut versus mechanically cut mesh are Ethicon internal documents and depositions. For example, Dr. Margolis cites internal Ethicon documents bates-labeled ETH.MESH. in support of his opinions that:

- “The method by which mesh is cut significantly impacts how that mesh will perform during the implantation surgery and while implanted in a woman’s body.” (TVT Rep. at 16; TVT-O Rep. at 16).
- “In a presentation by Ethicon’s engineer, Gene Kammerer, significant degradation in the form of fraying of the cut edges of the mesh and a loss of some of the edge particles was observed in the mechanically-cut mesh (MCM) after it had been elongated by 50%, while the TVT mesh that was laser-cut (LCM) demonstrated less particle loss, fraying and degradation.” (TVT Rep. at 16; TVT-O Rep. at 16).
- “[T]he mechanically-cut mesh also tends to more drastically rope, curl and deform when it is stretched or placed under tension. In the same presentation by

Kammerer, significant deformation, in the form of roping/twisting, and curling, was also observed in the mechanically-cut mesh (MCM) after it had been elongated by 50%, while the TVT mesh that was laser-cut (LCM) suffered some of the same deformation issues, but to a lesser degree.” (TVT Rep. at 17; TVT-O Rep. at 17).

- “Ethicon’s own testing revealed that laser cutting the mesh caused it to behave differently than mechanically-cut mesh, particularly with regard to its stiffness and elasticity. The studies showed that laser-cut mesh was indeed substantially stiffer and less elastic.” (TVT Rep. at 18 (citing “an internal [Ethicon] memo”); TVT-O Rep. at 18 (same)).

In short, Dr. Margolis has simply regurgitated company documents without any independent analysis or corroboration. He has failed to explain how company tests that artificially elongated the mesh by 50% had any bearing on how the mesh would react under normal circumstances in the human body. Moreover, he has pointed to no evidence that these observations indicate that the cut of the mesh could have any clinically significant impact once implanted. He has utterly failed to explain the scientific “literature” supporting his opinions on mechanically cut mesh and laser cut mesh in this case, relying only on corporate documents to support his opinions. This Court explicitly precluded Dr. Margolis (and other experts) from merely parroting what was in Ethicon’s corporate documents. *See* Dkt. 2681, at 12 (excluding Dr. Margolis from offering testimony “that is solely a conduit for corporate information”); *see also Hershberger v. Ethicon Endo-Surgery, Inc.*, 2012 WL 52444287, at *7-8 (S.D. W. Va. Feb. 15, 2012) (Johnston, J.) (excluding an expert from testifying as to product defect, where expert’s opinion was not based on his experience or education, but rather was based on other experts’ testimony and the defendant’s corporate documents); *Hines v. Wyeth*, 2011 WL 2680842, at *5 (S.D. W. Va. 2011) (Copenhaver, J.) (excluding expert testimony in part because it “merely regurgitates factual information that is better presented directly to the jury rather than through the testimony of an expert witness”).

Dr. Margolis does not cite any scientific literature in the section of his reports discussing mechanically cut mesh and laser cut mesh. He therefore has cited no reliable evidence to support his vague and unverifiable personal experience. (*See* TVT Rep. at 17 (“I personally have witnessed the same type of deformation of the mesh material.”); TVT-O Rep. at 17 (same)). His opinion that mechanically cut mesh results in more degradation and injury to a woman when implanted than does laser cut mesh is not supported by any personal statistical analysis or verifiable information, nor has he identified any scientific literature in support of his opinions. This testimony should therefore be excluded. (TVT Rep. at 16-18; TVT-O Rep. at 16-18).

II. The Court should exclude Dr. Margolis’s other opinions on degradation.

As Ethicon argued in its Wave 1 Motion to Exclude Dr. Margolis’s testimony, Dr. Margolis has, in a deposition in another pelvic mesh case, failed to identify any studies showing that TVT was capable of clinically significant degradation. *See, e.g.,* Ex. D, Margolis *Batiste* (11/26/13) Dep. 205:12-207:3 (failing to identify any studies showing that TVT was capable of clinically significant degradation). He also admitted that he had no clinical literature supporting his theory that degraded polypropylene mesh particles increase the inflammatory response. Margolis *Batiste* (11/26/13) Dep. 206:23-207:3. Ethicon acknowledges that the Court has distinguished *Batiste*, in which Dr. Margolis gave testimony admitting that he did not have scientific literature to support his degradation opinions. Instead, the Court observed that “[i]n this [Wave 1] case, . . . Dr. Margolis does support his opinions with citation to scientific studies and articles,” and further observed that because no particular article was challenged, the articles on which he relies in this case were not excludable on reliability grounds in Wave 1. *See* Dkt. 2681, at 6-7. Ethicon respectfully submits that the scientific literature on which Dr. Margolis relies for his degradation opinions is unreliable, and his opinions should therefore be excluded.

For example, in their response brief to Ethicon's Motion to Exclude Dr. Margolis's testimony in Wave 1, Plaintiffs pointed to a scientific article upon which Dr. Margolis supposedly relied for his opinion that degraded polypropylene mesh particles increase the inflammatory response, a study by the Long Beach Medical Center and the University of Louisville, Sternschuss, G., et al., *Post-Implantation Alterations of Polypropylene in the Human*, J. of Urol. At 31 (2012).¹ See Dkt. 2169, Pls.' Opp'n to Defs.' Mot. to Exclude Certain Opinions of Michael Thomas Margolis, M.D., at 10. Plaintiffs cite to this study for the following proposition:

[T]here is an immune response in the acute inflammatory phase, followed by the secretion of acid by macrophages, which attacks the mesh and starts the oxidative process already begun by the heat of the manufacturing process. The [polypropylene] degradation that follows releases additives in the [polypropylene] that enhance the inflammatory response.

Id. (article attached as Exhibit C to Plaintiff's Response).

But this study is unreliable for several reasons. It is fundamentally unreliable in the present litigation against Ethicon because it addresses polypropylene meshes in general, and not Prolene mesh. The distinction is crucial because polypropylene itself, as the articles notes, is prone to oxidation, and thus to some process of degradation. Prolene, on the other hand, is not prone to oxidation, because it contains proprietary additives, some of which are specifically designed to counter-act the oxidizing process²—the same process that this article and others

¹ Dr. Margolis claims degraded polypropylene mesh particles occur in greater number with mechanically cut mesh rather than laser cut mesh. See TVT Rep. at 16; TVT-O Rep. at 16.

² Ethicon is aware that this Court has previously questioned whether there is evidence that Prolene is distinct from other forms of polypropylene. See *Huskey v. Ethicon*, 29 F. Supp. 3d 691, 703 (S.D. W. Va. 2014). Even experts for Plaintiffs, however, have admitted that Prolene is different from other forms of polypropylene because it contains proprietary antioxidants. See, e.g., Ex. E, *Huskey*, 8/25/2014 Trial Tr. 156:14-18; 157:11-17 (Dr. Scott Guelcher—plaintiff's

contend causes “degradation.” In short, the comparison between polypropylene *in general*, as the Sternschuss article upon which Dr. Margolis relies, and Ethicon’s Prolene mesh, is an apples-and-oranges comparison. The Sternschuss article (the co-author of which, incidentally, is Dr. Donald. R. Ostergard, another expert for Plaintiffs, *see* Dkt. 2169, Exhibit C, at 27) does *not* address Prolene mesh and does *not* explain the impact that antioxidant additives have on polymer degradation relative to polypropylene mesh without such an additive. Neither does Dr. Margolis explain how the article’s conclusions might still be relevant to Prolene mesh that has been treated with antioxidants. Dr. Margolis’s opinions generally are insufficiently supported by articles addressing polypropylene mesh that is *not* Prolene mesh. *See* TVT Rep. at 10-12 (citing articles regarding “polypropylene mesh” and hernia mesh in support of his degradation opinions); TVT-O Rep. at 10-12 (same).

Moreover, the Sternschuss article itself is laced with speculation. For example, the articles authors speculate that certain processes create reactions, which “reactions *may* be responsible for alterations in the mesh, which *may* ultimately lead to deep cracking of the mesh surface and subsequent mesh failure.” *Id.* at 28 (emphases added). Indeed, the authors concede that “[g]enerally, we have no idea of exactly what was used in a particular mesh construct.” *Id.* Such an admission renders the article unreliable in forming opinions against a *proprietary mesh* designed to counteract oxidation. And although the study’s authors state that “degraded mesh produces undesirable consequences, leading to short-term and long-term complications, tissue damage, and organ function deterioration,” *id.* at 31, such a conclusion is pure *ipse dixit*. The article itself does not support with objective data the notion that degraded mesh causes clinical consequences, and it does not cite to any literature in support of this proposition. The following

biomaterials scientist—conceding that Prolene’s antioxidant package makes it unique from other forms of polypropylene); *see also* Ex. F, Guelcher 3/23/16 Dep. Tr. 87:23-88:9 (same).

paragraph acknowledges this conundrum by noting the “complex” nature of this issue. *Id.* Ethicon respectfully submits that the scientific literature upon which Dr. Margolis relies for his degradation opinions is unreliable. His testimony on this subject is equally unreliable and should be excluded.

CONCLUSION

Ethicon respectfully requests the Court grant their Motion to Exclude the Testimony of Michael Thomas Margolis, M.D.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on this day I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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